b.) Remarks

The title has been amended in order to more specifically relate to the pending claims. No new matter has been added.

Claims 1-5 and 8-12 stand rejected under 35 U.S.C. §103(a) as being obvious over Suzuki (U.S. Patent No. 5,587,378) in view of Trenkwalder (*Clinical Neuroscience* (1998)), both of record.

In support of the rejection, the Examiner states Suzuki teaches administering Applicants' preferred xanthine derivative (of claims 5 and 12) to Parkinson's Disease ("PD") patients. Suzuki does not explicitly teach using that compound to treat restless legs syndrome ("RLS") or nocturnal myoclonus ("NM") but Trenkwalder is cited as showing

> the frequency of sleep complaints with PD is estimated between 60-90% and a variety of either disease-related or secondary mechanisms and the various treatments contribute to the development of different sleep disturbances
>
> ...
>
> Trenkwalder teaches that restless legs syndrome frequently occurs in patients with Parkinson's disease at an advanced stage. Further, Trenkwalder teaches that another motor phenomenon that occurs in Parkinson's disease is nocturnal myoclonus.
>
> Therefore, it would have been obvious to one of ordinary skill in that art at the time of the invention to administer the compound(s) of formula I to PD patients as taught by Suzuki and used them to also treat patients with restless legs syndrome and nocturnal myoclonus because Trenkwalder makes it clear that these motor disturbances are commonly observed in individuals with Parkinson's disease. Thus if a patient with PD is administered the compound of formula I, it would be obvious that the

> restless legs syndrome and nocturnal myoclonus symptoms would also be treated. (Citations omitted; emphasis added.)

This rejection is respectfully traversed.

Even if the Examiner's statements are factually correct, the rejection is essentially without basis in law. That is, as recognized in the Office Action, the pending claims all recite treating RLS (claims 1-5) or NM (claims 8-12). None of these is taught by Suzuki (as acknowledged by the Examiner, Suzuki relates only to treating PD) so such cannot and is not relied upon for express anticipation. While Trenkwalder says *some* PD patients may also suffer from RLS or nocturnal myoclonus such is not necessarily and always true, so Suzuki alone cannot inherently anticipate the pending claims either.[1]

As to the asserted obviousness, however, Applicants respectfully submit the Examiner's rejection is factually incorrect. That is, while RLS and nocturnal myoclonus may be *associated with* certain stages of PD, the record does not at all establish either (i) there is suggestion or (ii) it is reasonable to use PD medication to treat RLS or NM.

By way of background, Applicants wish to explain that PD patients may exhibit ("present") a wide disparity of symptoms such as akinesia, bradykinesia, muscular rigidity and tremor, etc., any of which are exhibited, if at all, depending on various factors including the progress of PD, environmental stress, comorbidity, character of the patient,

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[1] To clarify the record, "sometimes" is not sufficient; to inherently anticipate a claim the reference must necessarily achieve the claimed results. *Glaxo Inc. v. Novopharm Ltd.*, 34 USPQ 2d 1565, 1567 (Fed. Cir. 1995) ("Inherency, however, may not be established by probabilities or possibilities. The more fact that a certain thing may result from a given set of circumstances is not sufficient.") See also *Continental Can Co. USA v. Monsanto Co.*, 20 USPQ 2d 1746 (Fed. Cir. 1991) and *Verdegaal Bros., Inc. v. Union Oil Co.*, 2 USPQ 2d 1051 (Fed. Cir. 1987).

and etc.[2]. As is very well-understood by those of ordinary skill in this art, RLS is simply one of many possible symptoms of PD.

In this connection, Tan et al., Restless Legs syndrome in Parkinson's disease, *J. Neurol. Sci.*, Vol. 196 (2002) 33-6 (of record)[3] teaches RLS and Parkinson's disease do not share the same pathophysiologic mechanism. As explained therein, drugs currently used for Parkinson's disease have the therapeutic effects on some of the symptoms of PD but not on all of the symptoms, and not on RLS or NM. Thus, even though Suzuki discloses that (E)-8-(3, 4-dimethoxystyryl)-1, 3-dimethyl-7-methylxanthine is useful for treating PD, irrespective of whether or not Trenkwalder teaches about the frequency of RLS in such patients, the skilled artisan has no expectation whatsoever that such adenosine A_{2A} receptor antagonist is useful for treating random disparate PD symptoms such as RLS and NM.[4]

To the contrary, the present invention is based on Applicants' unexpected discovery that an adenosine A_{2A} receptor antagonist such as (E)-8-(3,4-dimethoxystyryl)-1, 3-dimethyl-7-methylxanthine a beneficial the therapeutic effect on RLS and NM.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-5 and 8-12 remain presented for continued prosecution.

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2 *Harrison's Principles of Internal Medicine*, 15th ed. (2001) 2399-406.

3 See Information Disclosure Statement filed January 14, 2008.

4 In this regard, those of ordinary skill further understand that effects on RLS can not be observed by Suzuki's animal models such as MTPT-treated mice (Experimental Example 3), haloperidol-induced catalepsy (Experimental Example 4) and unilateral 6-OHDA-lesioned rat (Experimental Example 5).

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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